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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,188	07/11/2001	Edward M. De Robertis	510015-258	1059

7590 02/16/2005

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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/16/2005

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09/903,188	07/11/2001	Edward M. De Robertis	510015-258	1059

7590 05/27/2004
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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,188	DE ROBERTIS ET AL	
	Examiner	Art Unit	
	David S Romeo	1647	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 6-8, 11 and 12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>0402</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendments filed 11/17/2003 and 07/11/2001 have been entered.

Claims 6-8, 11, 12 are pending.

5

Applicant's election of group I, claims 6-8, 12, in Paper No./the paper filed 08/22/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

10

Applicant's election of the polypeptide encoded by SEQ ID NO: 10 or comprising the amino acid sequence of SEQ ID NO: 9 species in Paper No./the paper filed 12/08/2003 is acknowledged.

15

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No./the paper filed 08/22/2003.

20

Claims 6-8, 12 are being examined. Claim 12 is being examined only to the extent that it reads upon the polypeptide encoded by SEQ ID NO: 10 or comprising the amino acid sequence of SEQ ID NO: 9 species.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must
5 contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

10 It is acknowledged that the present application contains a specific reference to the 08/874,474 prior application in the first sentence of the specification. However, the specific reference to the 08/874,474 prior nonprovisional application does not include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications. The status of nonprovisional parent application(s) (whether patented or
15 abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If a benefit claim to a provisional application is submitted without an indication
20 that an intermediate application directly claims the benefit of the provisional application and the instant nonprovisional application is not filed within the 12 month period or the relationship between each nonprovisional application is not indicated, the Office will not recognize such benefit claim and will not include the benefit claim on the filing receipt.

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Therefore, a petition under 37 CFR 1.78(a) and the surcharge set forth in 37 CFR 1.17(t) will be required if the intermediate application and the relationship of each nonprovisional application are not indicated within the period set forth in 37 CFR 1.78(a). Even if the Office has recognized a benefit claim by entering it into the Office's database and including it on applicant's filing receipt, the benefit claim is not a proper benefit claim under 35 U.S.C. 119(e) or 35 U.S.C. 120 and 37 CFR 1.78 unless the reference is included in an ADS or in the first sentence of the specification and all other requirements are met. Accordingly, the benefit of the filing dates of the 08/874,474 nonprovisional application and the 60/020,150 provisional application is denied.

It is acknowledged that Applicants submitted a petition on 11/17/2003 to accept an unintentionally delayed claim for priority. However, that petition has been dismissed. See the paper mailed 05/21/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by De Robertis (N).

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This rejection is being made because the Office does not recognize Applicants benefit claims to the 08/874,474 nonprovisional application and the 60/020,150 provisional application, as discussed above.

De Robertis discloses a substantially pure protein characterized by a physiologically active form and comprising an amino acid sequence encoded by the DNA of SEQ ID NO: 10 (page 25, claim 6). De Robertis's SEQ ID NO: 10 is identical to the present application's SEQ ID NO: 10, as indicated below (Qy = the present application's SEQ ID NO: 10) (Db = De Robertis's SEQ ID NO: 10):

```
10  AAV14017
    ID  AAV14017 standard; cDNA; 1893 BP.
    XX
    AC  AAV14017;
    XX
    DT  09-JUL-1998 (first entry)
    XX
    DE  Human "frazzled" frzb-1 cDNA.
    XX
    NM  Growth factor; frazzled; frzb-1; Wnt3 antagonist; human;
    NN  tumour suppressor; cancer; ds.
    XX
    OS  Homo sapiens.
    XX
    PH  Key          Location/Qualifiers
    FT  CDS          61..1038
    FT              /tag= a
    FT              /product= frzb-1 protein
    XX
    PN  M09748275-A1.
    XX
    PD  24-DEC-1997.
    XX
    PF  19-JUN-1997; 97MO-US10942.
    XX
    PR  18-JUN-1997; 97US-0078474.
    PR  20-JUN-1996; 96US-0020150.
    XX
    RA  (REOC) UNIV CALIFORNIA.
    XX
    PI  Bounseester T. De Robertis SM;
    XX
    DR  MPI; 1998-062760/06.
    DR  P-PCDB; AAM41254.
    XX
    PT  New isolated growth factors - with neurotrophic, growth or
    PT  differentiation factor activity, tumour growth suppressor activity
    PT  or mesoderm differentiation activity
    XX
    PS  Claim 6; Fig 10; 48pp; English.
    XX
    CC  The present sequence encodes the human growth factor protein
    CC  "frazzled" frzb-1. frzb-1 is an antagonist of Wnt3 in vivo, and
    CC  thus is believed to find utility as a tumour suppressor gene,
    CC  since overexpressed Wnt proteins cause cancer. Frzb-1 may also be a
    CC  useful vehicle for solubilisation and therapeutic delivery of
    CC  complexed Wnt proteins.
    XX
    SQ  Sequence 1893 BP; 516 A; 438 C; 432 G; 507 T; 0 other;

60  Query Match          100.0%; Score 1893; DB 19; Length 1893;
    Best Local Similarity 100.0%; Pred. No. 0;
    Matches 1893; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

65  Qy      1 0000GAGCGGGCCCTTTTGGGCTCCACTGCGGGGCTGCACCGTCCCATCTGCCGGATC 60
    Db      1 0000GAGCGGGCCCTTTTGGGCTCCACTGCGGGGCTGCACCGTCCCATCTGCCGGATC 60
    Qy      61 ATGGTCTGGGCGAGCGGGGAGGATGCTGCTGCTGCGGGGCGGGGCTGCTTCCCTGGCT 120
    Db      61 ATGGTCTGGGCGAGCGGGGAGGATGCTGCTGCTGCGGGGCGGGGCTGCTTCCCTGGCT 120
```


[illegible]

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5 QY 1501 CTCTCTCTCTAGAAAAGTTCGAAATGTTTCTTAAAGTAAATGCGATTTGAAATCAA 1560
 Db 1501 CTCTCTCTCTCTAGAAAAGTTCGAAATGTTTCTTAAAGTAAATGCGATTTGAAATCAA 1560

10 QY 1561 TTTTCACTAGCCAAAGCGATCGAGCCAGGAGTGTCTTGAAGAAACACCCGAGA 1620
 Db 1561 TTTTCACTAGCCAAAGCGATCGAGCCAGGAGTGTCTTGAAGAAACACCCGAGA 1620

15 QY 1621 TGAATTATTTTGAAGCTGTCTGGAAGTAAATAAATAGAGCTTAAGAAAGAACATTTT 1680
 Db 1621 TGAATTATTTTGAAGCTGTCTGGAAGTAAATAAATAGAGCTTAAGAAAGAACATTTT 1680

20 QY 1681 GCGTGAATTGGAAGCAGCACTGAAAGCGATGAGCCCTGCGGTGTTAATGCTAGCATTTCT 1740
 Db 1681 GCGTGAATTGGAAGCAGCACTGAAAGCGATGAGCCCTGCGGTGTTAATGCTAGCATTTCT 1740

25 QY 1741 CTTTTCGCAATACATTTGATTTGTTCTGATATATATTATCAGCATTTAGAGAAATGATT 1800
 Db 1741 CTTTTCGCAATACATTTGATTTGTTCTGATATATATTATCAGCATTTAGAGAAATGATT 1800

QY 1801 ATAACTGAGACATCTGCTGTTTATCAGCATGTTTGTCTTAAATTTGCTTCTTTTAATAAA 1860
 Db 1801 ATAACTGAGACATCTGCTGTTTATCAGCATGTTTGTCTTAAATTTGCTTCTTTTAATAAA 1860

QY 1861 CCCATTGCTGAAAGTCAAAAAAAAAAAAAAAAA 1893
 Db 1861 CCCATTGCTGAAAGTCAAAAAAAAAAAAAAAAA 1893.

30 De Robertis's SEQ ID NO: 10 encodes the amino acid sequence of SEQ ID NO: 9
 and SEQ ID NO: 9 is the amino acid sequence of human frzb-1 (page 6, lines 29-31;
 Figures 9 and 10). De Robertis's SEQ ID NO: 9 is identical to the present application's
 SEQ ID NO: 9, as indicated below (Qy = the present application's SEQ ID NO: 9) (Db =
 De Robertis's SEQ ID NO: 9):

35 AAW41254
 ID AAW41254 standard; protein; 325 AA.
 XX
 AC AAW41254;
 40 XX
 DT 09-JUL-1998 (first entry)
 XX
 DE Human "frazzled" frzb-1.
 XX
 HN Growth factor; frazzled; frzb-1; Wnt antagonist; human;
 45 HN tumour suppressor; cancer.
 XX
 OS Homo sapiens.
 XX
 PN MO9746275-A1.
 50 XX
 PD 24-DEC-1997.
 XX
 PF 19-JUN-1997; 97MO-US010942.
 XX
 55 PR 20-JUN-1996; 96US-0020150P.
 PR 18-JUN-1997; 97US-00878474.
 XX
 PA (REOC) UNIV CALIFORNIA.
 XX
 60 PI De Robertis EM, Soummeester T;
 XX
 DR WPI; 1998-062760/06.
 DR N-PSDB; AAW41017.
 XX
 65 PT New isolated growth factors - with neurotrophic, growth or
 PT differentiation factor activity, tumour growth suppressor activity or
 PT mesoderm differentiation activity.
 XX
 70 PS Claim 6; Fig 9; 48pp; English.
 XX
 CC The present sequence is the human growth factor protein "frazzled" frzb-
 CC 1. frzb-1 is an antagonist of Wnt in vivo, and thus is believed to find
 CC utility as a tumour suppressor gene, since overexpressed Wnt proteins
 CC cause cancer. Frzb-1 may also be a useful vehicle for solubilisation and

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CC therapeutic delivery of complexed Wnt proteins

XX

SQ Sequence 325 AA;

5 Query Match 100.0%; Score 1738; DB 3; Length 325;
 Best Local Similarity 100.0%; Pred. Mo. 7.1e-165;
 Matches 325; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

10 QY 1 MWGSPQWELLERGLLALALCLLEVPGARAAACEPVRIPLCKSLPNDTTOEWHLHS 60
 DB 1 MWGSPQWELLERGLLALALCLLEVPGARAAACEPVRIPLCKSLPNDTTOEWHLHS 60

15 QY 61 TQAAALAIISQPEGLLOTHCSFLLPFLCANYAPICTIDFQSEPTKPCSVCEARQCE 120
 DB 61 TQAAALAIISQPEGLLOTHCSFLLPFLCANYAPICTIDFQSEPTKPCSVCEARQCE 120

20 QY 121 PILIKVRESMPENLACEHLFVYDGVGVCISPEAIVTADGADFPDSSNMCRASSERCIC 180
 DB 121 PILIKVRESMPENLACEHLFVYDGVGVCISPEAIVTADGADFPDSSNMCRASSERCIC 180

25 QY 181 KPIRATQKTYFSDNYVTVIRAKVKEIKTKCEDVTAVVEVKEILKSSLVMIPTDVELYTS 240
 DB 181 KPIRATQKTYFSDNYVTVIRAKVKEIKTKCEDVTAVVEVKEILKSSLVMIPTDVELYTS 240

30 QY 241 SOCLCPPLAVNERYIIMVYEDDSRLLLVDSIARNDKRLGKVKRQMDGLRLGLSK 300
 DB 241 SOCLCPPLAVNERYIIMVYEDDSRLLLVDSIARNDKRLGKVKRQMDGLRLGLSK 300

30 QY 301 SDSSNSDSTQSGKSGNSMPQARN 325
 DB 301 SDSSNSDSTQSGKSGNSMPQARN 325.

De Robertis also discloses a complex comprising a substantially pure frzb-1 protein complexed with at least one Wnt protein (claim 12, page 26). Accordingly, De Robertis discloses a complex comprising a substantially pure frzb-1 protein comprising the amino acid sequence of SEQ ID NO: 9 complexed with at least one Wnt protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

40 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

45

The present specification discloses that "substitutional, deletional, or insertional mutants of the novel polypeptides may be prepared by in vitro or recombinant methods and screened for immuno-crossreactivity with cerberus, frzb-1, or PAPC and for cerberus

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antagonist or agonist activity" (page 5, lines 31-35). Hence, it is unclear how to construe the term "frzb-1 protein" because it is unclear if "substitutional, deletional, or insertional mutants" are encompassed by the term "frzb-1 protein." The metes and bounds are not clearly set forth.

5

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

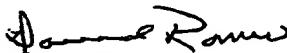
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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 26, 2004